

**CHILDREN ASTEPRO ALLERGY- azelastine hcl spray, metered
Bayer HealthCare LLC.**

Children's Astepro Allergy

Drug Facts

Active ingredient

Azelastine HCl 205.5 mcg (equivalent to 187.6 mcg azelastine)

Purpose

Antihistamine

Uses

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

Only for use in the nose. Do not spray in eyes or mouth.

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you

- have had recent nose ulcers or nose surgery
- have had a nose injury that has not healed

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- you may get a bitter taste in your mouth. To help avoid this, tilt your head downward while spraying.
- nasal discomfort or sneezing may occur right after use
- do not share this bottle with anyone else as this may spread germs

Stop use and ask a doctor if

- an allergic reaction, such as a skin rash, to this product occurs
- you have severe or frequent nosebleeds

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Read the User Guide for how to:

- prime the bottle before first use
- prime bottle again if not used for 3 or more days
- use the spray
- clean the spray nozzle if it gets clogged

adults and children 12 years and older	This product may be used either once or twice a day: <ul style="list-style-type: none">• <u>once daily</u>: use 2 sprays in each nostril; OR• <u>twice daily</u>: use 1 or 2 sprays in each nostril every 12 hours• do not use more than 4 sprays in each nostril in a 24 hour period
children 6 years to 11 years	<ul style="list-style-type: none">• an adult should supervise use• 1 spray in each nostril every 12 hours• do not use more than 2 sprays in each nostril in a 24 hour period
children under 6 years	do not use

Other information

Other information

- store between 20° to 25° C (68° to 77° F). Protect from freezing.
- keep this carton and the enclosed User Guide for important information
- do not use if tape printed with “sealed for your protection” on top and bottom carton flaps is not intact

Inactive ingredients

benzalkonium chloride, edetate disodium, hypromellose, purified water, sodium citrate, sorbitol, sucralose

Questions or comments

Questions or comments?

1-800-317-2165 (Mon-Fri, 9AM-5PM EST)



VARIABLE PRINT
AREA
Printing Process: Ink Jet
- Lot & EXP: Printed On-line
- EXP Format: YYYY/MM

Azelastine HCl 205.5 mcg per spray
 ANTIHISTAMINE NASAL SPRAY
 FULL PRESCRIPTION STRENGTH
 STERIOD FREE
 UP TO 24 HOUR RELIEF OF
 Nasal congestion
 Runny nose
 Sneezing
 Itchy nose

CHILDREN ASTEPRO ALLERGY

azelastine hcl spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-0066
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AZELASTINE HYDROCHLORIDE (UNII: 0L591QR10I) (AZ ELASTINE - UNII:ZQI909440X)	AZ ELASTINE HYDROCHLORIDE	205.5 ug

Inactive Ingredients	
Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-0066-03	22 in 1 BOTTLE	06/30/2022	
1		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0280-0066-01	60 in 1 BOTTLE	06/30/2022	
2		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:0280-0066-02	120 in 1 BOTTLE	06/30/2022	
3		1 in 1 CARTON; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA213872	06/27/2022	

Labeler - Bayer HealthCare LLC. (112117283)